

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: COLUMBIA UNIVERSITY
PATENT LITIGATION**

)
) **MDL NO. 1592**
)
)

**IMMUNEX CORPORATION, a
Washington Corporation and AMGEN
INC., a Delaware Corporation,**

) **CIVIL ACTION NO.: 04-10740-MLW**
) **C. D. Cal. No. CV 03-4349 (CWx)**
)

Plaintiffs,

) **Judge Mark L. Wolf**
)
)

vs.

**THE TRUSTEES OF COLUMBIA
UNIVERSITY in the City of New York, a
New York Corporation,**

Defendant

AND RELATED COUNTERCLAIM.

**RESPONSE OF PLAINTIFFS AMGEN INC. AND IMMUNEX CORPORATION TO
COLUMBIA'S MEMORANDUM OF JUNE 10, 2005 IN RESPONSE TO THE COURT'S
ORDER OF MAY 17, 2005**

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Amgen demonstrated in its June 10 Memorandum that its First and Seventh Claims and its Third Claim (as amended) survive the Court's dismissal order and should remain part of the MDL proceedings along with the Amgen Affiliates action. In its Motion to Consolidate, Amgen extensively briefed the common issues in the claims that survive the court's dismissal order in the MDL actions. Ignoring Amgen's compelling showing of commonality and directly contrary to Columbia's arguments which secured MDL consolidation, Columbia summarily contends that common issues do not exist to justify continued MDL proceedings. Columbia ignores Amgen's reliance upon the efficiency to be gained by continued proceedings in this Court in light of this Court's considerable expertise gained with the technology and patent issues in this MDL proceeding. Columbia did not -- because it cannot -- demonstrate that remand and lack of consolidation would further the just and efficient conduct of these actions.

I. AMGEN'S FIRST AND SEVENTH CLAIMS SURVIVE THE NOVEMBER 5, 2004 ORDER

By alleging that Amgen is "not required to pay royalties and fees for periods after August 16, 2000," *e.g.*, Second Amended Complaint ("SAC") at ¶ 62, Amgen's First and Seventh Claims broadly encompass royalties sought by Columbia under the prior expired Axel patents and are not limited to the royalties sought under the '275 patent (which did not issue until September 24, 2002). Moreover, as signaled by the use of the term "*inter alia*" in the First Claim, SAC at ¶¶ 61, 62, Columbia's egregious later-abandoned demand for royalties based on pending patent applications was but one "among other" examples of the basis for Columbia's demand which underlay Amgen's declaratory judgment claims. Because those claims are not limited to relief sought from payment of royalties under the '275 patent, they survive the Court's November 5, 2004 Order.

Columbia fails to cite any authority to support its supposition that Amgen is required to exemplify every basis underlying Columbia's demand for royalties, even though notice pleading under Fed. R. Civ. P. 8(a)(2) requires only a short and plain statement that Amgen is entitled to

declaratory relief from Columbia's demand. Instead, Columbia ignores that Amgen's First Claim for Relief broadly seeks a declaration that "no" royalties are owed, and further ignores that Amgen's reference to Columbia's demand based on pending patent applications was expressly provided as an "*inter alia*" example. Columbia does not deny that it seeks royalties on other bases, and that Amgen has always sought a declaration that "no" royalties are owed.

Instead, Columbia defends with the red herring that "in the face of an omnibus motion to dismiss, Amgen never argued that this declaratory relief claim [First Claim] pertained in any way to a demand for royalties under the original Axel patents" and that "[t]he *first* time Amgen made that assertion was *after* the Court granted Columbia's motion to dismiss." Columbia University's Report to the Court Pursuant to Order Dated May 17, 2005 ("Columbia Report") at 2-3 (emphases in original). Columbia is mistaken. In response to its "omnibus" "Emergency Motion to Dismiss" on September 2, 2004, Amgen filed on September 22, 2004 – well before the Court's ruling – an opposition that noted in pertinent part:

Columbia also ignores the fact that Amgen's First Claim for Relief is broader than merely addressing the question whether royalties are due to Columbia by reason of the pendency of patent applications (a claim Columbia has since abandoned). Amgen's First Claim for Relief seeks a declaration whether *any* royalties are owed after August 2000 under the parties' contract, whether by reason of pending patent applications *or otherwise*.

Amgen Memorandum in Opposition to "Emergency Motion to Dismiss" ("Amgen Opp."), Sept. 22, 2004, at 14 (emphases added).

Similarly, Columbia argues that Amgen's opposition to its "Emergency Motion" did not mention that Amgen's Seventh Claim (the "repressive practices" claim) could be broader than Columbia's demands for royalties under pending patent applications. Again, this is not so. The title of the Seventh Claim – "Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty Obligations Based on Columbia's Failure to Perform Condition" – introduces its breadth, which is not limited to only *some* of the royalties claimed by Columbia. The Seventh Claim plainly requests a declaration that Amgen's and Immunex's "obligation to pay additional royalties is

excused by reason of Columbia's failure to refrain from repressive practices." SAC at ¶ 91. This requested declaration was not limited, as Columbia contends, to royalties after September 24, 2002 when the '275 patent issued. Consistent with that plain meaning, Amgen opposed Columbia's motion to dismiss the Seventh Claim by arguing that "Amgen's claim for declaratory relief regarding contract rights remains," Amgen Memo. in Opp. to Emergency Motion to Dismiss, Sept. 22, 2004 at 2, and discussed significant common questions that would remain in the MDL, including "Columbia's repressive practices that excuse contractual performance by plaintiffs," *id.* at 14-15 – the practices at issue in Amgen's Seventh Claim.

Columbia argues that the Court should dismiss the Seventh Claim, ironically citing to the transferor court's order *denying* Columbia's motion to dismiss that claim. Columbia now argues that "the only allegation Amgen has ever pointed to in this regard is the claim that Columbia sought royalty payments on the basis of pending patent applications, as alleged in ¶ 58 and as discussed above." Columbia Report at 3. Again, this is not so. On the contrary, as demonstrated above, the repressive practices pleaded in the SAC are much broader than simply the demand based on pending patent applications in 2001,¹ and Amgen so explained in the transferor court,² which correctly *denied* Columbia's motion.

II. LEAVE TO AMEND SHOULD BE GRANTED

No prejudice or delay will result from granting Amgen leave to amend to refer to information newly discovered and events transpiring since filing of the SAC, especially where Amgen and Columbia have yet to exchange initial disclosures under Fed. R. Civ. P. 26(a)(1). Columbia claims

¹ For example, the facts alleged in the SAC which support Amgen's allegation that Columbia engaged in repressive practices include, *inter alia*, Columbia's failure to disclose, during prosecution of the prior expired '665 patent, material information in publications co-authored by named inventors. See SAC at ¶¶ 50-52.

² "Columbia's repressive practices occurred over a period commencing in the 1980's, including conduct well before Amgen ceased paying royalties." Memo. of Pts. and Auths., filed Jan. 12, 2004, Appendix A to Amgen's June 10, 2005 Memorandum, at 9, n. 6.

no futility, bad faith, undue delay or dilatory motive, nor any prejudice. Instead, Columbia rests its opposition on its mistaken belief that the entire Amgen case has been dismissed and statements taken out of context by this Court and the transferor court. None is an obstacle to the requested amendment.

Columbia's opposition to Amgen's Motion to Amend is grounded on the mistaken presumption that the Court dismissed all of Amgen's claims, when the May 17, 2005 Order contemplates otherwise by asking the parties to address whether the First and Seventh Claims *survive*. Because, as summarized *supra*, this is not a case where the action between Amgen and Columbia has been dismissed, Columbia's analogy to such actions lacks merit.

Columbia's reliance upon Judge Pfaelzer's order as precluding further amendment is belied by Columbia's own failure to cite the order when it requested at the June 22, 2004 Hearing that the Court permit Columbia to amend its pleadings and to set a cutoff date for further amendments (which the Court postponed doing). Judge Pfaelzer's January 27, 2004 Order denying Columbia's motion to dismiss Amgen's Seventh Claim stated that "[f]urther leave to amend will not be granted," but that order was made in the context of a dispute focused solely on a motion as to the Seventh Claim, and where Judge Pfaelzer intended a speedy pre-trial leading to a trial scheduled in 2004. It did not preclude amendment based on later-discovered facts without further analysis or justification, nor could she properly have done so.³ Furthermore, Judge Pfaelzer's ruling was superseded in this Court during the hearings on Columbia's motion to stay, when the Court *denied* Columbia's request to set a deadline for amendment of pleadings (which Columbia's Report fails to mention), and indicated that amendments to the pleadings were to be made after the obviousness-type double patenting portion of the case was completed, in January. *See* Excerpt of June 22, 2004 Hearing

³ The Supreme Court has held that "outright refusal to grant the leave [to amend] without any justifying reason appearing for the denial" is an abuse of discretion "inconsistent with the spirit of the Federal Rules." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

Transcript at 194:23-197:24, Exhibit 1 hereto.

This Court's statement on October 6, 2004 relied upon by Columbia, did not address, much less prejudice, any request by Amgen itself to amend. This Court's comment that Amgen could not move to amend at that time was a response to Amgen's question whether the *Amgen Affiliates* could file a new action as opposed to moving to amend to add them as parties. *See* Excerpt of October 6, 2004 Hearing Transcript, at 130-131, Exhibit 2 hereto. At that time, Biogen Idec had filed a new action, and Columbia had asserted that the filing was improper because Biogen's affiliate should have moved to amend under Rule 15. Rather than enter that controversy, Amgen asked for guidance, and the Court advised that Amgen's "affiliate can file its own case the way Idec did." *Id.* at 131. No question was before the Court regarding Amgen's *own* amendment of its complaint to supplement with later-occurring or later-discovered facts.

III. THE AMGEN AFFILIATES COMPLAINT SHOULD BE CONSOLIDATED WITH THE SURVIVING MDL CLAIMS

As Amgen demonstrated in its Motion to Consolidate and its June 10 filing, efficiency mandates that the Amgen Affiliates action be consolidated with the MDL proceedings. Columbia summarily asserts that "the Amgen Affiliate claims do not overlap with the surviving MDL claims," Columbia Report, at 9, without discussing any of the details of the overlap that have been extensively briefed by Amgen.⁴ For example, Columbia ignores that common facts are alleged both in the MDL plaintiffs' allegations of Columbia's repressive practices, *e.g.*, SAC at ¶¶ 29-57 (incorporated and realleged by reference in ¶ 88 of the Seventh Claim) and in the Affiliates' allegations that Columbia committed inequitable conduct which renders the '275 patent unenforceable, *e.g.*, Amgen Affiliates Complaint at ¶¶ 47-74. Similarly, allegations concerning

⁴ *See, e.g.*, Amgen's opening and reply memoranda on its motion to consolidate, attached as Appendices G and H to Amgen's June 10, 2005 Memorandum; Amgen Affiliates' Opposition to the Motion to Dismiss (Appendix L to Amgen's June 10, 2005 memorandum), at 5-6; and Amgen's June 10, 2005 Memorandum at 14-18.

Columbia's prosecution and licensing misconduct underlie both the MDL plaintiffs' and the Affiliates' claims that Columbia engaged in repressive practices and unclean hands.

Furthermore, the Affiliates action involves the same allegations of misconduct as those alleged in the surviving claims of Amgen and the other MDL plaintiffs. That the misconduct allegations of the Affiliates actions are relevant to the claims for relief concerning the '275 patent and the misconduct allegations of the surviving Amgen claims are relevant to claims for relief concerning the expired Axel patents is immaterial, particularly in light of this Court's finding that the '275 claims are likely not patentably distinct from claims in the prior expired Axel patents. *See* August 13, 2004 Memorandum and Order in Case No. 03-11329-MLW at 21 (finding likelihood of success that "plaintiffs are likely to satisfy that burden and prevail in proving that the '275 patent is invalid" for obviousness double-patenting). Columbia's failure to rebut Amgen's compelling showing of overlap demonstrates its inability to do so.

Columbia's opposition to consolidation for trial is premature and ignores both its own pleas for a consolidated trial⁵ and pending legislation that may allow consolidation for trial following pre-trial of these cases. *See* Amgen's June 10, 2005 Memorandum, at 13 n. 15.

IV. AMGEN'S CASE SHOULD NOT BE REMANDED

Columbia requested and obtained transfer and consolidation of these cases in this MDL proceeding to "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). Now, in a transparent attempt to avoid defending any Axel patent in this Court, Columbia seeks remand based only on conclusory assertions regarding the purported lack of overlap of issues in the remaining cases. In reality, the Court has committed significant resources to familiarize itself with the patent claims at issue in these cases and significant factual overlap remains, as discussed *supra*,

⁵ Columbia has repeatedly argued, and still does, that it wanted "to consolidate all actions in a single district where there would be one trial." Columbia Memo. in Supp. of Motion to Dismiss, *Biogen Idec Inc. v. Trustees of Columbia*, Action No. 04-CV-12009 MLW, Jan. 14, 2005, Appendix I to Amgen's Memo. filed June 10, 2005 at 4.

Section III, and in the briefs cited in n.4. Columbia therefore cannot meet its burden of showing that efficiency would not be furthered from further coordinated proceedings.

Columbia ignores Amgen's prior showing of commonality and summarily contends that there is "no relationship whatever" between Columbia's claim for further royalties from Amgen and the "validity or enforceability of the '275 patent, nor does Amgen claim otherwise." *Id.*, at 9-10. To the contrary, Amgen has repeatedly demonstrated the overlap of factual issues arising from the validity and enforceability of the '275 patent issues in the Amgen and Biogen Affiliates Complaints and the surviving claims of the MDL proceedings.⁶ As discussed above, for example, extensive common facts underlie Amgen's allegations that no royalties are owed based on Columbia's repressive misconduct during prosecution of the prior expired Axel patents, and the Affiliates' allegations that Columbia's '275 patent is unenforceable for inequitable conduct based upon the same misconduct.

Columbia relies upon the fact that Amgen is the only party against whom it has counterclaimed for royalties under the expired Axel patents. Although that is true, it is irrelevant to the remand analysis. Columbia's counterclaims have overlapping issues with very similar claims pleaded by Genentech, Wyeth, and Amgen and Biogen Affiliates for recoupment of royalties erroneously paid under or audit regarding the expired Axel patents. In fact, the Biogen Affiliates have a recoupment claim nearly identical to Amgen's based upon Columbia's breach of its most favored licensee obligations. Amgen, Wyeth and the Biogen Affiliates also have nearly identical defenses based upon Columbia's contractual obligation to refrain from engaging in repressive practices. All of these claims will require careful analysis of nearly identical license agreements and scrutiny of the claims of the prior expired Axel patents. Coordinated discovery should proceed

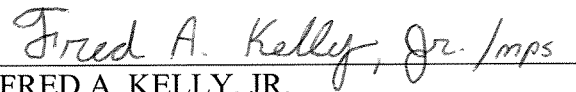
⁶ See note 4, *supra*.

on those common issues to promote the just and efficient conduct of those actions.

Dated: June 20, 2005

Respectfully submitted,

IMMUNEX CORPORATION, a Washington
Corporation and AMGEN INC., a Delaware
Corporation
By their attorneys,

Handwritten signature of Fred A. Kelly, Jr. in cursive script, with the initials 'Jr.' and 'Imps' at the end.

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